DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

0399 5 SEP 30 P2:14

Date: SEP 12 2005

From: Consumer Safety Officer, Division of Dietary Supplement Programs , Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: __Elastase (Pancreatopeptidase E)___ _____

Firm: __ OYC International, Inc._____

Date Received by FDA: __ June 22, 2005_____

90-Day Date: ___September 20, 2005_____

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

___*Victoria Lutwak*___

1995S-0316

RPT291

DEPARTMENT OF HEALTH AND HUMAN SERVICE Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

Ted Kottcamp
Director, Sales & Marketing
OYC International, Inc.
2 Elm Square
Andover, Massachusetts 01810

AUG 9 2005

Dear Mr. Kottcamp:

This is to inform you that the notification, dated June16, 2005, you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on June 22, 2005. Your notification concerns the substance "Elastase" also known as Pancreatopeptidase E that you intend to market as a new dietary ingredient.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

Federal regulations found at 21 CFR 190.6 specify the requirements for a pre-market notification for a new dietary ingredient. Your notification concerning "Elastase" does not comply with the requirements of 21 CFR 190.6 and is incomplete. The following items were not included with your submission: (1) A description of the dietary supplement or dietary supplements that contains your new dietary ingredient, (2) the level of the dietary ingredient in the dietary supplement and (3) the conditions of use recommended or suggested in the labeling of the dietary supplement. Your notification recommends "a maximum daily

intake of 60 mg per day" but does not provide a description of the dietary supplement that contains the new dietary ingredient including: the level of the new dietary ingredient in the dietary supplement.

Your notification provided only citations and abstracts of the references that you relied on as evidence of safety. Any references to published information offered in support of the notification shall be accompanied by reprints or photo static copies of such references. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation.

In addition, your notification did not include documented history of use of your new dietary ingredient as an article present in the food supply or as an article used for food in a form in which the food has not been chemically altered.

Your notification did provide some safety data for "Elastase" used as a drug but did not provide evidence of safety for the dietary supplement containing a new dietary ingredient. Thus, FDA cannot make an evaluation of the safety of "Elastase" based on the history of use information provided in your notification.

Moreover, from the information submitted in your notification, it appears that "Elastase" is intended to treat a medical condition. Please be aware that under 21 U.S.C. 321(g)(1)(B), if a product is implicitly or expressly represented as being intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease, it may be subject to regulation under the drug provisions of the Act. If you intend to make claims or representations of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER).

FDA is unable to determine whether the scientific studies cited in your notice provide an adequate basis for a conclusion that the dietary supplement will reasonably be expected to be safe because the information contained in your notice is incomplete. If you market your product without submitting a notification that meets the requirements of 21 CFR 190.6 (http://www.cfsan.fda.gov/~lrd/cfr190-6.html), or market your product less than 75 days after submitting such a notification, your product is considered adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of June 22, 2005. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Linda S. Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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http://www.oyc.co.jp

June 16, 2005

REC'D JUN 22 2005 / V.L

Ms. Vicki Lutwak
Acting Director
Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Dear Ms. Lutwak:

Notice hereby given pursuant to the requirements of 413 (a) (2) [(21 U.S.C.350b)] of the Federal Food, Drug, and Cosmetic Act of the intent of OYC International to introduce a new dietary ingredient, **ELASTASE (PANCREATOPEPTIDASE E),** (the "Ingredient"), into interstate commerce on or after October 1, 2005. Based upon the information available, we recommend a maximum daily intake of the Ingredient of 60 milligrams per day. The following documents evidencing the safety of the Ingredient are enclosed with this notice.

1. Elaszym® Tablet Clinical Evaluation (for reference purposes only)
    a. Precautions & Adverse Reactions
    b. Product Description
    c. Clinical Evaluation
    d. Pharmacokinetics
    e. Toxicity

If you have any questions or comments regarding this information, please contact Matt Matsukawa, Sr. Technical Manager, OYC International at (978) 470-1980.

Sincerely,

Ted Kottcamp
Director, Sales & Marketing
OYC International

A HEALTHIER WORLD
OYC
INTERNATIONAL, INC.